
As prescribed in 48 CFR 1335.006(b), insert the following clause:

**PROTECTION OF HUMAN SUBJECTS (APR 2010)**

(a) Contractor has satisfied the requirements set forth in solicitation #, related to the Protection of Human Subjects in research. The Government has determined that the research involving human subjects to be conducted under this contract is exempt from the requirements of the Common Rule for the Protection of Human Subjects.

(b) If the conditions upon which the exemption is based should change in any way, contractor shall immediately notify the Contracting Officer in writing. The Government will review the change and make a determination as to whether the change requires a change to the exemption approval. Contractor shall not proceed until notified in writing of the Contracting Officer’s approval. Contractor shall obtain prior written approval from the Contracting Officer for any change to the existing human subjects protocol or informed consent form before proceeding.

(c) Contractor has a valid Federal-wide Assurance (FWA) issued by OHRP; or

(d) The Federal Policy for the Protection of Human Subjects (the “Common Rule”), adopted by the Department of Commerce at 15 CFR Part 27, requires contractors to maintain appropriate policies and procedures for the protection of human subjects in research. The Common Rule defines a “human subject” as a living individual about whom an investigator conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The term “research” means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

(End of provision)

[75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010]
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(1) Copies of the human subjects research protocol, all questionnaires, surveys, advertisements, and informed consent forms approved by the cognizant IRB;

(2) Documentation of approval for the human subjects research protocol, questionnaires, surveys, advertisements, and informed consent forms by the cognizant IRB;

(3) Documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for agency institutional review and approval. The contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

No work involving human subjects may be undertaken, conducted, or costs incurred and/or charged to the project, until the Contracting Officer approves the required appropriate documentation in writing.

(End of clause)

(75 FR 10570, Mar. 8, 2010; 75 FR 14496, Mar. 26, 2010)


As prescribed in 48 CFR 1335.006(c), insert the following clause:

PROTECTION OF HUMAN SUBJECTS—INSTITUTIONAL APPROVAL (APR 2010)

(a) This contract/order includes non-exempt human subjects research that must be conducted pursuant to the requirements of the Federal Policy for the Protection of Human Subjects (the “Common Rule”), adopted by the Department of Commerce at 15 CFR part 27. Contractor has submitted documentation establishing review and approval of the human subjects research protocol, including all informed consent forms, advertisements, and other recruitment materials, by a qualified Institutional Review Board (IRB) that has a current Federal-wide Assurance (FWA) issued by the Department of Health and Human Services (DHHS).

(b) By accepting this contract/order, the contractor certifies the accuracy of the documentation provided to its cognizant IRB and to the Government in support of the human subjects research specified therein. Based upon the contractor’s documentation, and following the Government institutional review thereof, the following specific involvement of human subjects in research is hereby approved by the Contracting Officer:

Name of IRB: ____________________________

(IRB # _______)

Title of IRB Protocol: ____________________________

Recruiting Letter Approval Date (if appropriate): ____________

Consent Form Approval Date: ____________

Assurance of Compliance Number: ____________

(c) Unless incorporated by written contract modification approved by the Contracting Officer, no other involvement of human subjects in research under this contract may be undertaken or conducted, or costs incurred and/or charged to the project, except as specified in the study plan reviewed and approved by the cognizant IRB and Government. Therefore, if the contractor modifies a human subjects research protocol, advertisement, or informed consent form approved by the cognizant IRB, contractor shall submit a copy of all modified material, along with documentation of approval for said modification by the cognizant IRB, to the Contracting Officer for agency institutional review and approval. Contractor may not implement any IRB-approved modification without written approval by the Contracting Officer.

Documentation of continuing IRB approval is required each year by the renewal date assigned by the cognizant IRB. Documentation of continuing IRB approval must be submitted to the Government for review and approval as soon as it occurs. Continuing approval of the human subjects research must be obtained from the cognizant IRB and provided to the Government until the research is completed or terminated. The contractor may proceed with previously approved human subjects research, if any, under this contract while the Government is conducting continuing review and approval of the human subjects research protocol. In the event that the Government determines, during the course of its review, that the human subjects research in this contract is not in compliance with the regulations set forth at 15 CFR part 27, or this contract, the Contracting Officer may take the appropriate enforcement action, including disallowing costs, suspending or terminating the human subjects protocol or the contract, by notifying the contractor in writing.

(d) It is incumbent upon contractor to ensure that continuing IRB review approval occurs in accordance with 15 CFR part 27. In the event that continuing review approval does not occur as set forth by 15 CFR part 27, contractor is to notify the Contracting Officer immediately.